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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,554	02/22/2002	Hiroto Yoshii	B588-027	4281
26272	7590 05/30/2006		EXAMINER	
COWAN LIEBOWITZ & LATMAN P.C.			LIN, JERRY	
JOHN J TORRENTE 1133 AVE OF THE AMERICAS NEW YORK, NY 10036			ART UNIT	PAPER NUMBER
			1631	
			DATE MAILED: 05/30/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/081,554	YOSHII, HIROTO				
Office Action Summary	Examiner	Art Unit				
	Jerry Lin	1631				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	I. sely filed the mailing date of this communication. D. (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 05 Ap	Responsive to communication(s) filed on <u>05 April 2006</u> .					
2a) This action is <b>FINAL</b> . 2b) ⊠ This	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
3) Since this application is in condition for allowan	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) ⊠ Claim(s) 1-11 and 13-51 is/are pending in the a 4a) Of the above claim(s) 22-45,49 and 50 is/ar  5) □ Claim(s) is/are allowed.  6) ⊠ Claim(s) 1-11,13-21,46-48 and 51 is/are rejected.  7) ⊠ Claim(s) 5 is/are objected to.  8) □ Claim(s) are subject to restriction and/or	e withdrawn from consideration.					
Application Papers						
9) The specification is objected to by the Examiner	,					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1)  Notice of References Cited (PTO-892)  2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary					
<ul> <li>2) Into Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> <li>Paper No(s)/Mail Date <u>2 pages</u>.</li> </ul>	Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	te atent Application (PTO-152)				

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#### **DETAILED ACTION**

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# Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 2, 2006 has been entered.

#### Status of the Claims

Claims 1-11, 13-21, 46-48 and 51 are under examination.

Claims 22-45, 49 and 50 are withdrawn as being drawn to an unelected invention.

### Claim Objections

4. Claim 5 is objected to because of the following informalities: a comma is missing between the word "sequence" and "gives" in line 4 of the instant claim. Appropriate correction is required.

### Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6, 7, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 6 recites "calculating the entropy of each node present in the path" followed by a series of prepositional phrases separated by commas. It is unclear what these prepositional phrases are modifying. For example, they could be modifying the calculations themselves, the node, the path, or the previous prepositional phrase. Clarification via clearer claim language is requested.

Claim 7 recites the limitation "said node increases" in line 4. There is insufficient antecedent basis for this limitation in the claim. This term was not mentioned previously in the claim or in the claims from which it depends.

# Claims Rejected Under 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 1-6, 8-11, 13-21, 46 and 51 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Shannon et al. (US 6,251,588).

The instant claims are drawn to a method of identifying probe candidates for a use as a probe that hybridizes to a nucleic acid fragment that includes the steps of

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generating a tree, extracting partial base sequences, evaluating the specificity of the extracted sequences, determining the probe candidate, and outing the probe candidate. Furthermore, a node is understood as the intersection or terminating point of two or more lines or curves.

Shannon et al. discloses a method for predicting the potential of an oligonucleotide to hybridize to a target nucleotide sequence (Abstract). The following describes the depiction in Figure 2 and the corresponding description in the specification of Shannon et al. is noted.

First, a sequence ("target base sequence") is utilized to generate candidate probes ("partial base sequence") of every possible starting position (instant claims 1, 3, and 4 "generation step" and claim 2; Columns 6-7, lines 66-67 and 1-5, respectively; and Column 7, lines 19-23). An example of this generation of candidate probes is depicted (Columns 29-34) wherein the start position of each candidate probe is the "node" (the terminating point of two or more lines; refer to below definition) and the "root node" is located on the target base sequence (i.e. tree). In addition, the nodes are identified with the base sequence order in the target (root node is identified with the nodes) (instant claims 16 and 17; columns 29-34).

Second, parameters of each of these candidate probes (partial base sequences) is determined (instant claim 1 "extraction step"; Column 7, lines 5-16). Third, candidate probes that satisfy (i.e. cut-off values) a particular set of parameters or evaluation functions ("calculated specificity"; i.e. melting temperature, etc.) are evaluated/filtered (instant claim 1 "evaluation step", claim 5, claim 8; Column 7, lines 16-19; column 23,

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line 41 -column 26, line 12). In addition to the evaluation steps, each the entropy for each node is determined and compared to a cut-off value (instant claims 6 and 9; column 22, lines 14-65, Table 1; column 24, lines 12-35). Finally, candidate probes are selected as probes based upon the evaluation (instant claim 1 "determination step"; Column 26, lines 13-36). The inventors list particular parameters/thermodynamic factors (i.e. oligonucleotide size/length, melting temperature, entropy, etc.) to be applied in the steps of oligonucleotide evaluation and determination as probes for the target sequence (instant claims 18-21; Column 7, lines 5-19; Columns 13-14, lines 48-67 and 1-9, respectively; and Table 1). Oligonucleotides in the subset are clustered (grouped) along a region of the nucleotide sequence that is hybridizable to the target nucleotide and eliminated (filtered) (instant claims 10, 11, 13, 14, & 15; Column 7, lines 19-27; and Column 26, lines 13-36; column 28, lines 1-14). The disclosed method is indicated as being operated in a computer (instant claim 46 "information processing apparatus"; Columns 7-8, lines 47-67 and 1-8, respectively; and Column 28, lines 21-27) and outputting the data to printer (column 8, lines 1-8; column 39, lines 25-45). Finally the identified oligonucleotide sequences are used as probes in oligonucleotide arrays (instant claim 51, column 6, lines 22-44). Thus, Shannon et al. anticipates the instantly claimed invention.

9. Claims 47 and 48 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Boebert et al. (U.S. Patent Number 4,621,321).

Boebert et al. discloses a system and program that provides access to system files (Abstract), therefore allowing the computer to access and execute a system file (i.e. method of determining a probe candidate") (claim 47; Column 1, lines 21-35). Borbert et al. indicate that such computer program is stored on "storage medium" (claim 48; Column 12, lines 36-68). Thus, Borbet et al. anticipates the instantly claimed invention.

## Response to Arguments

10. The above 35 U.S.C. §102 rejections were previously applied in the Office Action dated February 9, 2005. Applicants had amended claims 1 and 46 to overcome the prior art. However, the amendments introduced NEW MATTER, as was noted in the Office Action dated November 2, 2005. In response to the NEW MATTER rejection, applicants withdrew the amendments. Without the amendments in the claims, the prior art used in the 35 U.S.C. §102 rejections is now applicable to the instant claims. Thus, the 35 U.S.C. §102 rejections from the Office Action dated February 9, 2005 are now reapplied.

#### Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Representatives are available to answer your questions daily from 6 am to midnight (EST). When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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> MICHAEL BORIN, PH.D. PRIMARY EXAMINER

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JL